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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17CA]

[Docket No. CDC-2016-0105]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project entitled "Positive Health Check Evaluation Trial." CDC is requesting a three-year approval for a data collection effort

designed to evaluate effectiveness of the Positive Health Check (PHC) online tool created by RTI and CDC. This CDC and Research Triangle Institute (RTI) developed tool delivers tailored evidence based prevention messages to HIV positive patients, on improving clinical outcomes and retention in care of HIV positive patients with unsuppressed viral loads. This data collection is also designed to assess the feasibility of implementing the intervention in clinics and the cost of the intervention.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0105 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read

background documents or comments received, go to
Regulations.gov.

Please note: All public comment should be submitted through the
Federal eRulemaking portal (Regulations.gov) or by U.S. mail to
the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on
the proposed project or to obtain a copy of the information
collection plan and instruments, contact the Information
Collection Review Office, Centers for Disease Control and
Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia
30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C.
3501-3520), Federal agencies must obtain approval from the
Office of Management and Budget (OMB) for each collection of
information they conduct or sponsor. In addition, the PRA also
requires Federal agencies to provide a 60-day notice in the
Federal Register concerning each proposed collection of
information, including each new proposed collection, each
proposed extension of existing collection of information, and
each reinstatement of previously approved information collection

before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete

and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Positive Health Check Evaluation Trial - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

HIV transmission continues to be an urgent public health challenge in the United States. According to CDC, approximately 1.2 million people are living with HIV, with close to 50,000 new cases each year. Antiretroviral therapy (ART) suppresses the plasma HIV viral load (VL) and people living with HIV (PLWH) who are treated with ART—compared with those who are not—have a substantially reduced risk of transmitting HIV sexually, through drug sharing, or from mother to child. However, it is estimated that only 19% to 28% of people who are infected with HIV in the United States have an undetectable HIV VL. To enhance HIV prevention efforts, implementable, effective, scalable interventions are needed that focus on enhancing prevention and care to improve the health of and reduce HIV transmission risk among PLWH. The Positive Health Check (PHC) intervention is based on earlier computer-based interventions that were proven

efficacious for HIV prevention.

The PHC intervention approach is innovative in multiple ways. First, it uses an interactive video doctor to deliver tailored messages that meet specific patient needs related to adherence, sexual risk reduction, engagement in care, mother-to-child transmission, and drug use. Second, this intervention is designed specifically to support patient behavior change by providing useful tips to practice between visits. These tips are patient driven and populated on a handout while patients use the PHC intervention, thereby increasing engagement and the likelihood of success. Third, PHC supports patient-provider communication by also generating a set of questions that patients would like to ask their provider. These behavior change tips and questions are also populated on a Patient Handout that patients may share with their provider. As such, PHC supports patients and providers during their clinical encounter and promotes communication. Finally, the PHC intervention has been designed from the onset for wide-scale dissemination. Its flexible digital strategy provides access on multiple devices and platforms. This approach makes PHC an important intervention strategy to improve public health in communities that have a high incidence of HIV infection.

This data collection has four primary aims: (1) implement a randomized trial to test the efficacy of the PHC intervention

for improving clinical health outcomes, specifically viral load and retention in care; (2) conduct a feasibility assessment to determine strategies to facilitate implementation and integration of PHC into HIV primary care clinics; (3) collect and document data on the cost of PHC intervention implementation; and (4) document the standard of care at each participating clinic. The awardee of this cooperative agreement is RTI. RTI has subcontracted with four clinical sites to implement the trial. The sub-contractors are the Atlanta VA Medical Center (Atlanta, Georgia), Hillsborough County Health Department (Tampa, Florida), Rutgers Infectious Disease Practice (Newark, New Jersey), and Crescent Care (New Orleans, Louisiana). The four clinical sites are well suited for this work, given the high rates of patients with elevated viral loads.

During the 24-month implementation period, 1,010 patients will be enrolled into the trial (505 intervention arm and 505 control arm) across the four clinics to evaluate the effectiveness of the PHC intervention. To assess the effectiveness of the PHC intervention, patients randomized to the intervention arm will provide their responses to the patient tailoring questions embedded within the intervention and all enrolled patients will consent to have their de-identified clinical values be made available via passive data collection

via the electronic medical record. In addition to the main trial, three to five key staff at each clinic site will be selected to participate in the PHC feasibility assessment which includes an online survey and qualitative interviews.

Finally, clinic staff who participate in the implementation of the PHC intervention will provide data on the cost of implementing the PHC intervention. It is estimated that the total burden hours for all data collection activities is 315.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hours)	Total Response Burden in (Hours)
Persons eligible for study	PHC intervention trial consent	505	1	5/60	42
	Staff online survey consent	20	1	5/60	2
Enrolled participants	PHC tailoring questions	505	3	5/60	126
	Online clinic staff survey	20	3	15/60	15
	Clinic staff qualitative interview	20	3	40/60	40
	Non-research labor cost questionnaire	12	3	75/60	45
	PHC labor cost questionnaire	12	3	75/60	45

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hours)	Total Response Burden in (Hours)
Total					315

Leroy A. Richardson
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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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